

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

CASE NO. 4:24-CR-00010 RLW/SPM

UNITED STATES OF AMERICA

vs.

MOHD AZFAR MALIK, M.D.

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**REPLY IN SUPPORT OF DR. MALIK'S  
MOTION TO DISMISS THE INDICTMENT (DOC. 55)**

Mohd Azfar Malik, M.D., through undersigned counsel, and pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B)(v), submits this reply in support of his motion to dismiss every Count in the Indictment for failure to state a claim (ECF 55). Despite contending that Dr. Malik's motion to dismiss "incorrectly assert[s] that the Indictment misrepresents th[e] federal regulations" on which it is premised, ECF 65-1 at 1, the Government either concedes that Dr. Malik's interpretation is correct or elides inconvenient regulatory language. And despite repeatedly contending that Dr. Malik has relied on matters outside the Indictment, the Government either ignores that Dr. Malik has relied on the plain allegations of the Indictment in support of his motion or raises its own extrinsic factual arguments to bolster its claims. For the reasons set forth in the Motion to Dismiss and below, every Count in the Indictment should be dismissed.

## ARGUMENT

### **A. The Indictment Does Not Properly Allege that Dr. Malik Maintained Drug Involved Premises in Violation of the CSA.**

In its response in opposition, the Government confirms its belief that Dr. Malik's alleged failure to obtain a separate registration for Cedar Plaza Building Suite 220 is a violation of 21 C.F.R. § 1301.12 that can serve as a basis for Counts 1 and 22. ECF 65-1 at 8. The Government's theory fails as a matter of law because Dr. Malik's conduct reasonably fell within the plain language of 21 C.F.R. § 1301.12, which requires practitioners to obtain separate DEA registrations for "each principal place of business or professional practice at one general physical location where controlled substances" are dispensed. As explained in Dr. Malik's Motion to Dismiss, Dr. Malik maintained a DEA registration at Cedar Plaza Building Suites 300 and 350,<sup>1</sup> one floor above COPE Ketamine Clinic in Suite 220. Under the plain terms of the regulation, Dr. Malik complied with the registration requirement because his registration at the Cedar Plaza Building covered "one general physical location" including Suite 220 where he administered or supervised the administration of controlled substances.

The Government accuses Dr. Malik of reading "each" out of 21 C.F.R. § 1301.12, but in fact, it is the Government's argument that reads "one general physical location" out of the regulation. As discussed in the Motion to Dismiss, "general" ordinarily

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<sup>1</sup> The Indictment alleges that the registration was changed from Suite 300 to Suite 350 in 2023. Indictment ¶ 9. The Government takes issue with the fact that the Motion to Dismiss only referenced Suite 350, *see* ECF 65 at 9 n.2, and so we add both suite numbers here to be comprehensive. The point of the Motion to Dismiss remains unchanged.

means “not particularized.” ECF 55 at 5 (quoting Black’s Law Dictionary (6th ed. 1990)). A suite number is particularized. A single building in which a physician’s practice utilizes several suites is not, and it is to account for this type of situation that DEA included the “one general physical location” language in the regulation.<sup>2</sup> A better reading of the regulation that gives meaning to every word included therein is that a separate registration is required for “each principal place of business” where controlled substances are dispensed (*i.e.*, if a doctor has multiple offices at different locations within the state), but only one registration is required for each “general physical location” where a doctor practices (*i.e.*, one registration per building).

The Government’s citation to 21 C.F.R. § 1301.12(b)(3), which refers to “[a]n office used by a practitioner (who is registered at another location in the same State in which he or she practices),” supports Dr. Malik’s reading, as it indicates that the regulation is aimed at ensuring practitioners with disparate offices across the *state* obtain a separate registration for each. This is how the regulation is enforced in practice. All enforcement actions we have identified have involved controlled substances being dispensed miles or states away from the practitioner’s place of registration. It is telling that the Government, too, is apparently aware of no enforcement action—administrative, civil, or criminal—involving a failure to obtain an additional DEA registration within the same building—because the Government does not cite a single one. Relying solely on the language in the Indictment, it is clear

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<sup>2</sup> Compare 21 U.S.C. § 822(e)(1) (“professional practice where . . .”) with 21 C.F.R. § 1301.12 (“professional practice at one general physical location where . . .”).

that Dr. Malik was properly registered at “one general physical location” and that, to the extent that the Government relies (as it concedes) on an alleged violation of 21 C.F.R. § 1301.12, Counts 1 and 22 should be dismissed.

Attempting to avoid this inevitable conclusion, the Government raises facts outside of the Indictment. This is ironic, given the Government’s repeated (and wrong) complaint that Dr. Malik has raised factual allegations that cannot be considered on a motion to dismiss. First, the Government’s argument about “a large medical building on a hospital campus,” ECF 65-1 at 10, is not based on the facts alleged in the Indictment. The Indictment alleges that Dr. Malik indirectly owns the Cedar Plaza Building and controls at least three suites within it, as pointed out in the Motion to Dismiss. *See* ECF 55 at 3-4. It is telling that the Government relies on a counterfactual example to try to defeat the plain meaning of the phrase “one general physical location” as applied to the facts alleged in the Indictment.<sup>3</sup> Second, the Government claims that it has evidence, not contained in the Indictment, that Dr. Malik ignored a warning that Suite 220 needed a separate registration. ECF 65-1 at 12. Yet the Indictment alleges that Dr. Malik *did* obtain separate DEA registrations when his office locations could not be considered “one general physical location.” *See* Indictment ¶ 10 (alleging that Dr. Malik obtained separate registrations for PCC locations not located within the Cedar Plaza Building). In other words, the

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<sup>3</sup> Moreover, the Government fails to cite a single enforcement action that would support even the hypothetical case it imagines.

Indictment itself alleges that Dr. Malik acted in conformity with the “one general physical location” language of the registration requirement.

If the Court nevertheless finds that there are factual issues outside of the Indictment that must be decided to determine whether the Cedar Plaza Building was “one general physical location” for purposes of 21 C.F.R. § 1301.12, then Counts 1 and 22 should be dismissed for vagueness. *See City of Chicago v. Morales*, 527 U.S. 41, 62 (1999) (finding an “inherently subjective” criminal standard void for vagueness); *Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (criminal laws must have “sufficient definiteness that ordinary people can understand what conduct is prohibited”). The Government’s reliance on *United States v. Clinical Leasing*, 925 F.2d 120 (5th Cir. 1991), is misplaced. That case, which involved a *civil* complaint against a clinic that dispensed controlled substances at least three miles away from one of its lead physicians’ place of registration, involved a vagueness challenge to the term “each principal place of business,” not the term “one general physical location,” which is the basis of Dr. Malik’s argument. To our knowledge, no court has yet considered a vagueness challenge to the “one general physical location” question, and certainly not in the context of a clinic located in the exact same building where a physician holds a DEA registration. If that does not constitute “one general physical location” as a matter of law, then the language of the regulation is plainly ambiguous and should not be permitted to support a federal criminal prosecution.<sup>4</sup>

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<sup>4</sup> Our reply in support of our Motion to Dismiss the Drug Trafficking counts explains why the Government’s “direct supervision” argument fails and is incorporated herein.

**B. The Government Rightly Concedes That Noncompliance with the Spravato REMS Program Cannot Serve as the Basis for Counts 1, 5, and 6, But Invokes a Legally Flawed Theory of Scienter.**

In its response in opposition, the Government concedes that the Spravato “REMS Program requirements ... do not serve as the legal basis for Counts 1, 5, and 6.” ECF 65-1 at 14. Of course not, because a REMS Program—which imposes statutory obligations only on the drug manufacturer—cannot give rise to criminal liability on the part of providers. But that is the point.<sup>5</sup> The Spravato REMS healthcare provider agreement, part of the manufacturer’s implementation of the Spravato REMS, is an agreement between a particular clinic and the Spravato manufacturer. The manufacturer is responsible for compliance with its REMS Program. To the extent the Government is unsatisfied with the implementation of a REMS Program, its remedy is against the manufacturer, not against the physician. Recognizing this does not, contrary to the Government’s argument, require the Court to decide whether Dr. Malik complied with the REMS requirements; it simply requires the Court to consider the law. And on this note, it is telling that the Government also has not found a single case in which a prosecution involved an alleged failure to comply with the requirements of a REMS Program. *See* ECF 55 at 8.

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<sup>5</sup> On this point, the REMS requirements quite clearly do serve as the legal basis for Counts 5 and 6 and Count 1 insofar as it is based on Spravato treatments. Indeed, what are the points of paragraphs 18-21 and 45 of the Indictment otherwise? The Government’s attempt to rewrite paragraph 46 (mistakenly cited as paragraph 45) in its Opposition, ECF 65-1 at 13, does not change this. The Government’s concession that the REMS requirements cannot form the legal basis for Counts 1, 5, and 6 is fatal to these Counts.

Recognizing that alleged REMS noncompliance cannot support any claim against Dr. Malik, the Government argues instead that the Spravato REMS Program requirements are nevertheless relevant to Dr. Malik’s “criminal intent.” *Id.* But because a violation of the REMS requirements cannot serve as the basis for Counts 1, 5, and 6, Dr. Malik’s alleged criminal intent as to those Counts is irrelevant and cannot save them from a motion to dismiss.

**C. Dr. Ali Provided “Annual Wellness Visit” and “Incident To” Services To Dr. Malik’s Existing Patents Under Dr. Malik’s Direct Supervision.**

The Government appears to take the position that Medicare will only approve a claim submitted by the person who directly provides a service and that submitting a claim for payment for a service performed by a person acting under the supervision of a “legitimately enrolled Medicare provider” is per se a material misrepresentation to Medicare about who performed the services. *See* ECF 65-1 at 14-15. But this is not the law. As discussed in our Motion to Dismiss, the relevant regulations allow for submission of claims for payments related to (1) Annual Wellness Visits performed by a health professional working under the direct supervision of a physician and (2) “incident to” services provided by auxiliary personnel acting under the direct supervision of a physician. CMS expects such claims to be submitted in the name of the supervising physician. *See* 75 Fed. Reg. 73170, 73401 (Nov. 29, 2010) (“our intent is that where the wellness visit is performed by a ‘team of medical professionals working under the supervision of a physician’ it is the supervising physician who would bill Medicare Part B for the visit”); 42 C.F.R. § 410.26(b)(5) (“[O]nly the supervising physician ... may bill Medicare for incident to services.”). Therefore, as

a matter of law, the Government cannot premise Counts 2 and 15–21 on Dr. Malik submitting a claim for payment for services performed by Dr. Ali under his supervision, as it incorrectly appears to believe.

In light of this, if and only if Dr. Malik “was [not] immediately available to provide virtual assistance to Ali whenever necessary” for purposes of the “direct supervision” requirement can he have committed the crimes charged in Counts 2 and 15-21. ECF 65-1 at 14. On this note, it is important that the Government concedes one of the key points from Dr. Malik’s Motion to Dismiss: that direct supervision included “virtual presence through audio/video real-time communications technology” during the relevant time period of the Indictment. *See* ECF-55 at 11. Contrary to the Government’s argument that the Court would have to consider extrinsic factual evidence to decide the Motion to Dismiss on these grounds, the Indictment itself alleges that Dr. Ali and Dr. Malik agreed that Dr. Malik could make himself available by telephone when Dr. Ali was treating Dr. Malik’s patients. *See* Indictment ¶ 43. The Counts therefore can be dismissed.

The Government’s position regarding Dr. Ali’s suspension from Medicare is puzzling. First, it is puzzling that the Government raises Dr. Ali’s suspension from Medicare in relation to the Annual Wellness Visit payments. Even assuming that Dr. Ali’s suspension from Medicare should have resulted in his Medicare enrollment being revoked, this is not relevant to Annual Wellness Visits. Unlike “incident to” billing, Annual Wellness Visit regulations contain no carve-out for supervised practitioners who have had their Medicare enrollment revoked. *Accord* 75 Fed. Reg.



73170, 73401-02 (Nov. 29, 2010) (“We believe it is better for the supervising physician to assign specific tasks to qualified team members (as long as they are licensed in the State and working within their state scope of practice).”). Accordingly, whether Dr. Ali did or did not have his Medicare enrollment revoked is irrelevant to Counts 15-19 and Count 2 insofar as it is premised on Annual Wellness Visits, and those Counts should be dismissed.

Second, the Government’s continued insistence that “should have been revoked” means “was revoked” is puzzling. As pointed out in the Motion to Dismiss, the regulatory definition of auxiliary personnel applies to Counts 20-21 and Count 2 insofar as it is premised on “incident to” billing. The auxiliary personnel definition includes a requirement that such individual “has not had his or her Medicare enrollment revoked.” ECF-55 at 13. But the Indictment alleges that, at all relevant times, Dr. Ali was enrolled in Medicare and had **not** had his Medicare enrollment revoked. See Indictment ¶¶ 29, 32. Even though the Government thinks Dr. Ali’s Medicare enrollment **should have been** revoked, the Indictment concedes it was **not**.<sup>6</sup> The Government cannot go back in time and change the status of Dr. Ali’s

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<sup>6</sup> In opposing this argument, the Government takes another puzzling position, that the Motion to Dismiss has raised an issue “outside of the pleadings.” ECF 65-1 at 6 n. 6. Not so. The Motion to Dismiss relied on the allegation in paragraph 32 of the Indictment that Dr. Ali’s enrollment in Medicare had not been revoked and then simply explained that, in any event, suspension from a state Medicaid program, as alleged in the Indictment at ¶ 30, is insufficient to revoke Medicare enrollment under the Medicare Program Integrity Manual. Whether or not Dr. Ali knew that he was required to disclose his Medicaid suspension to Medicare as the Government asserts in its Opposition (ECF 65-1 at 6 n. 6) (but not in the Indictment, ironically) is quite irrelevant as to whether Dr. Ali’s Medicare enrollment had, as a factual matter, been revoked.

enrollment based on what it believes it should have been. And despite the Government's apparent contention to the contrary, *see* ECF 65-1 at 15, auxiliary personnel are not required to be independently enrolled in Medicare at all, *see* 42 C.F.R. § 410.26(a)(1), so long as they are providing services within the scope of their licensure under the direct supervision of a physician who is enrolled with Medicare. *See* ECF 55 at 13-15. Thus, under the facts specifically alleged in the Indictment, Dr. Ali's services could properly be billed by Dr. Malik, despite the Government's "illegitimacy" concerns. Counts 2 and 20-21 should therefore be dismissed.

Respectfully submitted,

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